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In re Application of :
Lipps et al :
Serial No.: 10/716,982 :
Filed : 19 November 2003 :
Attorney Docket No.: FWLPAT019US :

Decision on Petition

This letter is in response to the Petition under 37 C.F.R. 1.181 filed on 6 September 2006 requesting review of the restriction requirement.

**BACKGROUND AND DISCUSSION**

The examiner mailed out a restriction requirement on 8 May 2006 dividing the original 22 claims into three groups. The examiner considered that the three groups were unrelated, however, a review of the independent claims 1, 21 and 22 (reproduced on the last two pages) which are divided among group I, II and III show that the three groups are all directed to processes of using antibodies to detect cancer markers in human saliva. All three groups require the same essential active step bringing together a reagent containing antibodies made against proteomic cancer markers with a saliva sample.

On 30 May 2006, applicant elected Group I with traverse. Applicants argued that the three inventions were related as disclosed and not independent.

On 7 August 2006, a second examiner considered the traversal, made that restriction requirement final and then set forth a second restriction requirement as to a series of election of species disclosed in the specification. The examiner does not point to any particular table, page or figures which discloses the various "objectives, method steps, and/or dosages and/or schedules used, response variable and criteria for success," etc from which applicants must chose. Moreover, the election of species requirement did not set forth reasons for distinction or burden.

With regard to the first restriction requirement, overlap in scope between claims is addressed in two sections of the MPEP, 806.03 and 806.04(f).

MPEP 806.03 Single Embodiment, Claims Defining Same Essential Features

> Where the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are not directed to distinct inventions; rather they are different definitions of the same disclosed subject matter, varying in breadth or scope of definition.

MPEP 806.04(f) Restriction Between Mutually Exclusive Species

> Where two or more species are claimed, a requirement for restriction to a single species may be proper if the species are mutually exclusive. Claims to different species are mutually exclusive if one claim recites limitations disclosed for a first species but not a second, while a second claim recites limitations disclosed only for the second species and not the first. This may also be expressed by saying that to require restriction between claims limited to species, the claims must not overlap in scope.

Groups I, II and III are closely related in terms of active steps, modes of operation, products used and outcome. The processes of Claim 21 and 22 could have been re-written to depend upon from claim 1. Groups I, II and III are related inventions and should be examined together.

With regard to the election of species requirement, again, the Office has not established burden, or distinction or even identified the species from which applicant should chose. No election of species requirement is warranted for this application.

**DECISION**

For the above reasons, the petition filed under 37 CFR 1.181 is **GRANTED**.

The restriction requirements mailed 8 May 2006 and 7 August 2006 have been withdrawn. The application will be forwarded to the examiner to prepare an action on the merits on the claimed invention.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 571-273-8300.

John LeGuyader
Director, Technology Center 1600

Relevant Claims

1. A process comprising

a) bringing together a reagent containing antibodies made against a mixture of proteonic cancer markers with a human saliva sample to form an assay sample, and

b) determining whether an immunological reaction has occurred in the assay sample.

21. A cancer diagnostic method comprising

a) obtaining a saliva specimen from a patient,

b) forming a saliva sample from the saliva specimen,

c) separating the saliva sample into a plurality of portions,

d) bringing the portions of the saliva sample together with a plurality of reagents, a single reagent being brought together with each portion, each reagent containing a separate slate of antibodies made against proteonic cancer markers from different types of cancer cells, one type of cancer cells being used to form each slate of antibodies, to form a plurality of assay samples;

e) conducting a simple ELISA test on each of the plurality of assay samples to obtain an ELISA test result on each of the plurality of assay samples,

f) identifying a most highly positive test result, and

g) associating the most highly positive test result with the type of cancer cells used to produce the antibodies yielding such results to provide the diagnosis.

22. A method for monitoring effectiveness of cancer treatment, said method comprising

a) obtaining a first saliva specimen from a patient,

b) forming a first saliva sample from the first saliva specimen,

c) bringing the first saliva sample together with a reagent containing antibodies made against at least one proteonic cancer marker made from a single cancer cell line to form a first assay sample,

e) conducting a simple ELISA test on the first assay sample to obtain a first ELISA test result on the first assay sample,

f) treating the patient for a cancer represented by the cancer cell line used to make the proteonic cancer marker, and, after a period of time of at least one week,

g) obtaining a second saliva specimen from the patient,

h) forming a second saliva sample from the second saliva specimen,

i) bringing the second saliva sample together with the reagent to form a second assay sample,

j) conducting a simple ELISA test on the second assay sample to obtain a second ELISA test result on the second assay sample, and

k) comparing the second ELISA test result with the first ELISA test result to determine the effectiveness of the cancer treatment.